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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/737,633	11/15/96	SAMARITANI	F [illegible]-60

EXAMINER

HM22/0307

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ART UNIT	PAPER NUMBER
FITZGERALD,D	22

DATE MAILED: 03/07/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 3-10 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1, 3, 5-7, 9, 10 is/are rejected.
☒ Claim(s) 4, 8 is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: CPA of Fra.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

1. Applicant's amendments in the reply filed 20 December 1999 have obviated the rejections under 35 U.S.C. § 112, second paragraph, set forth in the last Office action (¶ 3 of the Office action mailed 2 July 1999, Paper No. 19).

Insofar as the rejections of record are maintained below, applicant's arguments filed 20 December 1999 have been fully considered, but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. The following rejections under 35 U.S.C. § 103 are maintained for the reasons set forth at the indicated paragraphs of Paper No. 19 and below:

Claims 1, 3, 7, 9, and 10, over Hanisch '566 (¶ 4);

Claim 5, over Hanisch '566 in view of Cymbalista '454 (¶ 5);

Claim 6, over Hanisch '566 in view of Hershenson '605 (¶ 6).

Applicant argues that Hanisch relates only to compositions comprising dextrose, not mannitol. This argument is not supported by the reference, which expressly teaches that mannitol is a suitable polyol for use as a stabilizer, as is dextrose, according to the invention it claims. '566 at col. 9, lines 31-37.

In traversal of the rejections, it is urged that the amended claims patentably define over the prior art because they recite an upper concentration limit of 24 x 10^6 IU ml^{-1}, roughly half the concentration employed by Hanisch in the formulation described in its Example 1. The examiner does not agree.

Example 1 of Hanisch describes a unit dose formulation containing IFN-β at 0.25 mg, or 50 x 10^6 IU. '566 at col. 21, lines 15-24. That is not however the only unit dosage known in the art. Hershenson '605, for example, teaches that a solution containing 0.25 mg ml^{-1} IFN-β is suitable for preparing "normal dosage" formulations, whereas a "high dosage" formulation will contain on the order of 2 mg ml^{-1}, and a "low dosage" formulation, 0.125 mg ml^{-1} of IFN-β. '605 at col. 8, lines 47-60. Hanisch, moreover, exemplifies the preparation of a formulation having only 0.06 mg of IFN-β. '566 at col. 24, lines 34-38.

It would have been obvious to prepare a formulation of IFN-β containing only half the amount exemplified by Hanisch at Example 1, *i.e.*, on the order of about 0.125 mg or 25 x 10^6 IU per vial, because Hershenson teaches that a range of unit dosages are employed in the art for

pharmaceutical preparations of IFN-β and that a solution of 0.125 mg ml^{-1} affords an exemplary "low dose" formulation. It would have been obvious to do so either by using half as much solution as described in Hanisch Example 1 or by preparing a solution containing IFN-β at half the exemplified concentration. The artisan would have expected the latter approach to be suitable for lyophilization according to the method of the '566 patent because Hanisch exemplifies a stable lyophilized preparation containing only 0.06 mg, or *ca.* 12.5 x 10^6 IU, of IFN-β.

3. The examiner believes that he has addressed all pertinent arguments. No claim is allowed. Claims 4 and 8 are objected to as depending from rejected base claims but would be allowable if rewritten in independent form, including all the relevant limitations of base claim 1.

As allowable subject matter has been indicated, Applicant's response must either comply with all formal requirements or specifically traverse each requirement not complied with. In particular, **formal drawings are required in response to this Office action.** See 37 C.F.R. § 1.111(b) and § 707.07(a) of the M.P.E.P.

4. Insofar as the rejections discovered above may be considered new grounds, applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

*A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED. ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(A) WOULD THEN BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.*

5. Any inquiry concerning this communication should be directed to David Fitzgerald, who can be reached by any of the following means:

Telephone (703) 308-3934

Fax
All formal papers (703) 308-4242
Informal communications (703) 308-0294

e-mail (note PTO policies below) david.fitzgerald@uspto.gov

Inquiries of a general nature should be directed to the Technology Center 1600 receptionists at (703) 308-0196.

DAVID L. FITZGERALD
PRIMARY EXAMINER
ART UNIT 1646

4 March 2000

The best **time to reach Examiner Fitzgerald** is from 9 a.m. to 4 p.m. (Eastern). If he cannot take a call, a message may be left on his voicemail. Should attempts to reach him be unsuccessful, the supervisor for this Art Unit, Gary Kunz, may be reached at (703) 308-4623.

Most official papers and all informal **communications may be submitted to the PTO by fax.** For specific policies, refer to 37 C.F.R. § 1.6 and the notice published at 1096 O.G. 30. To facilitate their receipt and handling, please —

- Call the examiner when you send an urgent communication.
- **Do not send a duplicate copy** by mail or courier.

Any Internet **e-mail communications will be made of record in the application file.** PTO employees cannot engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. § 122. This policy is more fully set forth in the Interim Internet Usage Policy published in the PTO's *Official Gazette* on 25 February 1997 at 1195 O.G. 89.